Activists hail report on HPV vaccines, but PATH says no violations

Report points to a serious dereliction of duty by many of the institutions involved

Updated - November 17, 2021 03:42 am IST

Published - September 03, 2013 03:05 am IST - NEW DELHI

Aarti Dhar

PRINT

Health activists have appreciated the Parliamentary Standing Committee's report on the "Alleged Irregularities in the Conduct of Studies Using Human Papilloma Virus (HPV) Vaccine by PATH in India." They commended "its candid, transparent contents, which reflect the committee's acknowledgement of the unethical nature of the HPV trials'' conducted in the country.

In the trials, Program for Appropriate Technology in Health (PATH), with the support of Bill and Melinda Gates Foundation (BMGF), approval from the Western Institutional Review Board (WIRB) [all three private international parties], donations from Merck Sharp and Dohme (MSD) and Glaxo SmithKline (GSK), in partnership with Indian Council of Medical Research (ICMR) and along with the governments of Andhra Pradesh and Gujarat, through the national vaccination programme, delivered and administered HPV vaccines to 10-14-year-old girls in Khammam (A.P.) and Vadodara (Gujarat) districts.

The committee's findings are wide-ranging: the nature of the project, the role of ICMR, the role of the Drugs Controller General of India (DCGI), the Informed Consent Process, the role of Ethics Committees (EC), the process of inquiry committee formation and function and the role of PATH.

The report points to a serious dereliction of duty by many of the institutions involved. In particular, it questions the role of the ICMR, DCGI, EC members and PATH.

The committee clearly stated that the demonstration project was a clinical trial, no matter what PATH called it.

The report said, "The demonstration project is a study of a pharmaceutical product carried out on humans and since the primary objective includes the study of serious adverse events, it is clear that clinical trial rule should apply."

A statement issued jointly by Jan Swasthya Abhiyan, Sama – Resource Group for Women and Health, and LOCOST / All India Drug Action Network said PATH, by carrying out clinical trials on the pretext of observation/demonstration project, has violated all laws and regulations laid down for clinical trials by the government.

Though, the committee brought up insurance to the girls, it has not mentioned the compensation in its report from the sponsor or an ex-gratia to the parents of the girls who died after the administration of the trial, the statement said, while demanding that the parents and children be compensated for the grave violations of their rights, as clearly informed consent was not taken from a large number of parents and no assent was taken from the girls who were given the HPV vaccine, and no follow-up or proper management of adverse events and serious adverse events during the trial was done.

"We welcome the recommendations and sincerely hope the contents and recommendations of the 72nd report by the Parliamentary Standing Committee will be acted upon, that there will be concrete early follow-up and outcomes of the committee's observations and recommendations," the statement said.

PATH stand

Reacting to the report, PATH said it was troubled by the report's "inaccurate characterisation of this important work."

"PATH, a non-profit organisation, is committed to meeting the highest scientific, ethical, and legal standards in our work and to contributing our experience and expertise to address the burden of cervical cancer through transformative innovations such as vaccines, a statement issued by it said.

"The demonstration project in India was part of a four-country project to explore suitable vaccine delivery strategies and help provide evidence for national health authorities to make informed decisions about the potential benefits and challenges of introducing vaccines against HPV, the primary cause of cervical cancer,'' the statement said.

ICMR approval

PATH said ICMR reviewed and approved the protocol for this project, including its design and methodology. At the time of its review, the ICMR determined the project was a post-licensure observational study and not a clinical trial.

"The project did not seek to evaluate the efficacy or long-term safety of the vaccines, which had undergone clinical evaluation in India and had been licensed and approved by the Drugs Controller General of India.''

ICMR's view was crucial, as it established the approval processes and protocols for the work that followed. PATH designed the project protocols in compliance with ICMR's instructions and fully complied with ICMR's requirements regarding the necessary approval processes and the requirements of the State governments regarding consent processes, according to the statement.

"We believe that by following the guidance provided by ICMR, as well as the two State governments and three ethical review committees, we designed a project that met or exceeded the country's existing regulatory standards for demonstration projects while providing the greatest health benefit to Indian women,'' PATH said.

Read Comments

PRINT